

### **REMARKS**

Applicant respectfully requests reconsideration and allowance of claims 1-10 that are pending in the above-identified patent application. In view of the following discussion, Applicant submits that all pending claims are in condition for allowance.

#### **Rejections Under 35 U.S.C. § 103(a):**

##### **U.S. 5,871,010 (hereinafter referred to as “the ‘010 patent”)**

Independent claim 1 recites “sloped and/or tapered parabolic-shaped elevations and/or depressions in a repeating pattern of an egg-carton arrangement”. (Emphasis added.)

In response to Applicant’s September 12, 2008 remarks, the Examiner alleges that the ‘010 patent does not teach away from the present invention of the instant application because the ‘010 patent teaches “minimizing” the surface area of contact. The Examiner alleges that the ‘010 patent has several variations of elevations and depressions, each embodiment having a varying degree of minimizing the surface area of contact, such that not all embodiments create the smallest possible area of contact. Applicant respectfully disagrees with the Examiner.

As maintained from Applicant’s September 2008 remarks, the elevations and/or depressions as claimed in independent claim 1 of the instant application are structurally different than any raised areas or indentations disclosed or suggested in the 5,947,118 patent (hereinafter referred to as “the ‘118 patent”), the ‘010 patent, and the 5,472,143 patent (hereinafter referred to as “the ‘143 patent”). With regard to the ‘118 patent and the ‘143 patent, the Examiner previously conceded that the ‘118 and the ‘143 patents do not disclose or suggest elevations and/or depressions as claimed in the instant application. As presented in Applicant’s May 9, 2008 response and maintained in Applicant’s September 2008 remarks, the ‘010 patent does not disclose or suggest sloped and/or tapered parabolic-shaped elevations and/or depressions as claimed in the instant application because the raised areas or indentations of the ‘010 patent device are not sloped and/or tapered between the surface of the substrate and the raised areas or indentations.

The Examiner improperly interprets a ‘decrease’ in contact as a ‘minimization’ of contact. As maintained from the September 12, 2008 response, Webster’s Unabridged Third New International Dictionary (2002) defines ‘minimize’ as “to reduce to the smallest [and not smaller]

possible number, degree, or extent”. (Emphasis added.) Indeed, minimization means more than to decrease because minimization means to decrease to the smallest extent possible. Although the Examiner alleges that adding indentations and/or raised areas as taught by the ‘010 patent to the interior flat surfaces of the ‘118 patent would decrease the area of contact, Applicant maintains from Applicant’s May 9, 2008 remarks with the supplemental Figure, and Applicant’s September 12, 2008 remarks that a mere decrease is not sufficient because the ‘010 patent teaches and requires minimization. As such, the Examiner improperly interprets the teachings of the ‘010 patent to only require a decrease and not a minimization.

The Examiner is improperly interpreting the ‘010 patent to avoid consideration of the portions of the ‘010 patent that lead away from the claimed invention of the instant application. The ‘010 patent teaches variations of elevations and depressions because the ‘010 patent teaches that various particles sizes may be selected. From col. 2, lines 32-35, the ‘010 patent states that “the width of the indentations or valleys have a diameter that is about 5% to about 20% smaller and more preferably, about 10% to about 20% smaller than a minimum selected particle size to be administered...” (Emphasis added.) Further, from col. 2, lines 38-44, the ‘010 patent states that “the depth of the indentations or valleys is also smaller than a minimum selected particle size...about 5% to 50% smaller, and more preferably, about 5% to 20% smaller...” (Emphasis added.) Indeed, the ‘010 patent teaches to select a minimum particle size for an embodiment of the ‘010 patent, and then to select a width and depth for the indentations or raised areas of the ‘010 device. As aforementioned, the ‘010 patent lacks any teaching regarding a sloped and/or tapered indentation or raised area for a selected minimum particle size. Once a minimum particle size is selected, the ‘010 patent teaches the same principle of operation for all surfaces of the substrate, i.e., the area of contact between the medicament and all the surfaces of the inhaler is minimized, regardless of whether the width and depth of the indentation or valleys of the raised areas is, for example, 5% or 20% smaller than the selected particle size.

The Examiner improperly ignores the teach away of the ‘010 patent, and therefore improperly fails to consider the ‘010 patent in its entirety while maintaining the rejections of the claims of the instant application. The ‘010 patent teaches away from employing sloped and/or tapered elevations and/or depressions as claimed in the instant application. According to MPEP §2141.02(VI), “[a] prior art reference must be considered in its entirety, i.e., as a whole, including

portions that would lead away from the claimed invention.” *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). As maintained from Applicant’s September 12, 2008 remarks, taking the ‘010 patent as a whole, the teachings of the ‘010 patent apply the same principle of operation, i.e., minimizing the area of contact between the selected medicament and all surfaces of the inhaler, for all surfaces of the substrate, and not just in comparison to a flat surface with no grooves. From at least the abstract, col. 1, lines 32-38; col. 2, lines 55-57; and col. 5, line 9 through col. 6, line 25, the ‘010 patent teaches minimization via indentations or raised areas. Specifically, from col. 1, lines 32-38, the ‘010 patent states that “at least one of such interior surfaces have indentations or raised areas therein...[to] provide a mechanism for minimizing the area of contact between the medicament and the surfaces of the inhaler”. (Emphasis added.) From col. 5, lines 9-12 and col. 5, lines 22-26, respectively, the ‘010 patent further supports such a minimization modification by stating that “[t]he inhaler substrate is preferably modified to minimize the surface area of the contact between the particles of the powder and the surface of the substrate...”, and “[t]he surface area of contact can be minimized, for example, by providing indentations in the plane of the surface, or by providing raised areas in the plane of the surface.” (Emphasis added.) Indeed, the ‘010 patent teaches modifying the surfaces of the inhaler to minimize the contact between the medicament and the surfaces of the ‘010 patent device, regardless of whether the surface already has indentations and/or raised areas or is flat.

As maintained from Applicant’s September 12, 2008 remarks, the teachings of the ‘010 patent disqualify the use of sloped and/or tapered elevations and/or depressions as claimed in the instant application. Applicant established in the May 9, 2008 response that the supplemental Figure submitted therewith depicts the particles and surface of the ‘010 device in accordance with col. 6, lines 12-17 of the ‘010 patent. As depicted in the May 9, 2008 supplemental Figure, the surface area of the present invention as claimed in independent claim 1 in contact with the particle is not minimized because the surface of the device of the ‘010 patent achieves even less contact, i.e., is minimized as taught in the ‘010 patent. Because the ‘010 patent teaches indentations or raised areas having the smallest or minimized contact with the medicament, those skilled in the art reading the ‘010 patent would not arrive at the present invention because the teachings of the ‘010 patent disqualify sloped and/or tapered elevations and/or depressions as claimed in independent claim 1 of the instant application as a minimization possibility. Indeed, those skilled in the art would not

employ the sloped and/or tapered elevations and/or depressions as claimed in the instant application because such elevations and/or depressions would increase the contact area between the medicament and the surfaces of the inhaler when compared with the indentations or raised areas as taught by the '010 patent. Therefore, such a comparison would result in those skilled in the art employing the indentations or raised areas of the '010 patent, and not as claimed in the instant application.

As maintained from Applicant's September 12, 2008 remarks, the specification of the instant application does not imply that the sloped/tapered shape of the invention is not a critical feature. On the contrary, the Examiner is not considering the specification of the instant application as originally filed in its entirety. From page 22, lines 1-5, the specification of the instant application states that "[t]he properties of the surfaces thus obtained are optimum when the elevations have rounded tips." (Emphasis added.) Indeed, rounded tips as taught in the specification of the instant application have a sloped/tapered shape, and thus, the specification of the instant application explicitly teaches that the sloped/tapered shape of the instant invention is a critical feature. Because the '010 patent teaches away from the invention as claimed in independent claim 1 of the instant application and because different functionality and a critical teaching exists in the specification of the instant application, the teachings of the '118 patent, the '010 patent, and the '143 patent cannot, and do not, result in the present invention as claimed in independent claim 1 of the instant application. In view of the above, Applicant submits that independent claim 1 is, therefore, patentable. As claims 2-7, 9, and 10 depend from independent claim 1, and recite additional patentable features, claims 2-7, 9, and 10 are, therefore, likewise patentable.

#### **U.S. 4,889,114**

In the Office Action at page 5, the Examiner has rejected claim 8 under 35 U.S.C. § 103(a) as being unpatentable over the '118 patent, the '010 patent, and the '143 patent in further view of U.S. Patent No. 4,889,114 ("the '114 patent"). The '114 patent does not cure the aforementioned deficiencies regarding independent claim 1, from which claim 8 depends. Therefore, Applicant submits that claim 8 is, therefore, likewise patentable.

In view of the above, Applicant respectfully requests that the Examiner's §103 rejections be withdrawn.

**Conclusion:**

In view of the foregoing, Applicant submits that the instant claims are in condition for allowance. Early and favorable action is earnestly solicited. The fee for the RCE and petition is included herewith. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

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Respectfully submitted,

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